

2008

Ambulatory Surgical Centers Annual Report



March 2009

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LETTER FROM THE ADMINISTRATOR

Shortly after I was appointed as the Health Division Administrator in late January 2008, the unimaginable happened. Southern Nevada Health District officials identified the potential exposure of over 40,000 patients to Hepatitis C. It was traced to unsafe injection practices related to the administration of anesthesia at two ambulatory surgical centers (ASCs) in Las Vegas.

The Health Division immediately adopted targeted emergency regulations and undertook focused surveys of all fifty licensed ASCs statewide, with assistance from four infection control and epidemiology experts from the Centers for Disease Control and Prevention. The incident highlighted the need for improving the regulation of our health care system, particularly ASCs.

During regular briefings to the Legislative Committee on Health Care regarding this matter, it occurred to me that an annual report on ASC licensure and certification activities would be a transparent way to communicate what the Health Division was doing to ensure safe, quality health care in Nevada. The intent of this first annual report is to provide policymakers, state and local agencies, the health care industry, professional associations, and the public with an overview of the agency's ASC licensure and certification efforts, the current state of regulatory oversight, sustainable improvements implemented, accomplishments achieved, lessons learned, and related goals for the future. The Health Division is also taking the necessary steps to make this information available to the public and easy to access as part of a long-range vision to transform Nevada's health care system by placing quality and safety first.

I hope that you find this draft version of the 2008 ASC Annual Report informative and insightful. As a draft, I welcome your comments and feedback, and look forward to working to fulfill your requests for additional information relating to the topic areas of your interest. A feedback form is attached at the end of the report for your convenience.

Sincerely,



Richard Whitley, MS, Administrator
Health Division

EXECUTIVE SUMMARY

This first annual report provides information concerning the regulation of ambulatory surgical centers (ASCs) in Nevada. Regulated by the State Board of Health and State Health Officer, pursuant to Nevada Revised Statutes (NRS) 439 and 449, the actual licensure and certification of these facilities are done by the Health Division's Bureau of Health Care Quality and Compliance (BHCQC)¹. The data provided is based on either a calendar year (CY) or state fiscal year (SFY), depending on availability.

In 2008, Nevada experienced an unimaginable event. Over 40,000 patients, who had received medical procedures at two southern Nevada ASCs, were identified by Southern Nevada Health District (SNHD) officials as being potentially exposed to Hepatitis C. The exposure was traced to unsafe injection practices related to the administration of anesthesia medication at two ambulatory surgical centers (ASCs).

This event also highlighted the inadequate inspection frequency of key medical facilities in our health care system, including ASCs. There were several contributing factors: 1) staffing issues due to difficulty recruiting facility surveyors; 2) poor communication between the Health Division and the licensed facilities; and 3) a survey process that did not have a public health focus. However, the primary reason for the less than optimal periodicity of health facility inspections, particularly of ASCs, was the priority given to the survey demands of the federal Centers for Medicare and Medicaid Services (CMS), which places ASCs at the bottom of the priority list for surveys. While the Health Division was responsible for meeting its CMS contractual obligations for Medicare initial certification surveys and recertification surveys (i.e., inspections), the CMS priorities were not balanced with state needs. Despite what happened in Nevada and is happening elsewhere in the U.S., CMS has not changed its priorities to reflect more frequent surveys of ASCs.

The Health Division has 5 years of data from survey findings, although until this report, no comprehensive analysis or trending had been done. The data have been used in a limited fashion to affect changes in the quality of care being provided by certain facilities. The data currently available is largely for skilled nursing facilities because of the priority CMS gives to such facilities other than ASCs. During the 2009 Legislative Session, the Health Division is requesting the staff necessary for ongoing data analysis, identification of areas for quality improvement, and fulfillment of education and training needs.

The Hepatitis C outbreak presented many challenges to the Health Division, as well as to other state agencies with health care regulatory responsibilities and to the very health care system itself. While many changes were required, many more will be implemented.

¹ Formerly known as the Bureau of Licensure and Certification (BLC)

VIRAL HEPATITIS

Causes, Transmission, and Outcome

There are five causative agents of viral hepatitis²: HAV, HBV, HCV, HDV, and HEV. However, both HDV and HEV are uncommon or rare in the United States. Hepatitis A is an acute illness contracted by ingestion of infectious fecal material. In contrast, Hepatitis B and C are transmitted via infectious blood, semen, or other bodily fluids and may manifest as either an acute or chronic infection, though Hepatitis C often becomes a chronic illness. Hepatitis C afflicts more than 3 million Americans.

Vaccines are available for both Hepatitis A and B, yet none have been developed for Hepatitis C. Infection with Hepatitis C is serious and potentially life-threatening. Beyond just hepatitis, it can lead to cirrhosis³ of the liver and/or liver cancer.

Viral Hepatitis in the Health Care Industry

In the United States, transmission of Hepatitis B and C from health care exposures is uncommon. However, a review of outbreak information revealed that there were 33 outbreaks in non-hospital health care settings in the past decade: 12 in out-patient clinics, 6 in hemodialysis centers, and 15 in long-term care facilities, resulting in 448 persons acquiring either HBV or HCV infection⁴. In each setting, the putative mechanism of infection was patient-to-patient transmission due to the failure of health care personnel to adhere to fundamental principles of infection control and aseptic technique, reusing syringes or lancing devices, for example.

Difficult to detect and investigate, such outbreaks suggest a wider and growing problem in certain segments of the health care industry as services are increasingly being provided in out-patient settings where infection control training and oversight may be inadequate. A comprehensive and systemic approach is needed to ensure that patients receive quality out-patient health care services free of the risk of infection with any form of hepatitis. Such an approach must include better surveillance and case investigation, health care provider education and training, professional oversight, licensure and certification, and greater public awareness.

² *Viral Hepatitis*. CDC. US DHHS. Available at <http://www.cdc.gov/hepatitis/>. Accessed on 2009.2.27.

³ Scarring of the liver.

⁴ *Nonhospital Health Care–Associated Hepatitis B and C Virus Transmission: United States, 1998–2008*. *Annals of Internal Medicine*. v 150. n 1. p 33–39. 2009.1.6.

HEPATITIS C OUTBREAK IN LAS VEGAS

Outbreak Investigation

In January 2008, the potential exposure of over 40,000 patients to Hepatitis C was first discovered. Southern Nevada Health District (SNHD) officials investigating two acute cases of the illness had linked them to the Endoscopy Center of Southern Nevada (ECSN), both the result of routine colonoscopy procedures.

Working with CDC, additional acute Hepatitis C cases were identified, all occurring in patients who had undergone endoscopic procedures in 2007 at ECSN. The source of infection was determined to be unsafe injection practices including the reuse of syringes and repeated use of single-dose vials. While the facility had corrected its unsafe practices by January 17, 2008, the Health Division found that the facility still failed to meet CMS standards in the categories of “Governing Body and Management” and “Pharmaceutical Services.” Therefore, the facility was placed on a 90-day CMS termination track, a written plan of correction was requested, and state sanctions were also put in place.

On January 31, 2008, an affiliated facility, the Desert Shadow Endoscopy Center (DSEC), underwent a recertification survey by the Health Facilities section of the BHCQC. It was found to be in violation of Medicare standards in the categories of ‘Governing Body and Management’, ‘Medical Staff’, and ‘Pharmaceutical Services’. Like ECSN, the facility was placed on a 90-day termination track with a plan of correction required, and sanctions were imposed. Both of these facilities had been accredited by national third-party accrediting organizations.

On February 27, 2008, SNHD and the Health Division held a joint press conference to discuss the findings at ECSN. At that time, SNHD notified the public that it had sent out approximately 40,000 individual letters of notification to patients who had received services at the facility since 2004. The notices recommended that former patients be screened for Hepatitis B and C, as well as HIV. The Health Division also assisted in the notification process by setting up a toll-free number with the Rocky Mountain Poison Control Center to help answer patient questions. A technical bulletin on unsafe injection practices was then prepared by the State Epidemiologist and distributed to all health care facilities and practitioners.

As a consequence of their role in the Hepatitis C outbreak, both the Endoscopy Center of Southern Nevada and the Desert Shadow Endoscopy Center had their business licenses revoked by the City of Las Vegas, and a \$500,000 fine was also assessed. SNHD also established a Hepatitis C Exposure Registry in June 2008, in an effort to track and document the spread of Hepatitis C, Hepatitis B, and HIV which may have resulted from the poor infection control practices at the two facilities.

Statewide Facilities Investigation

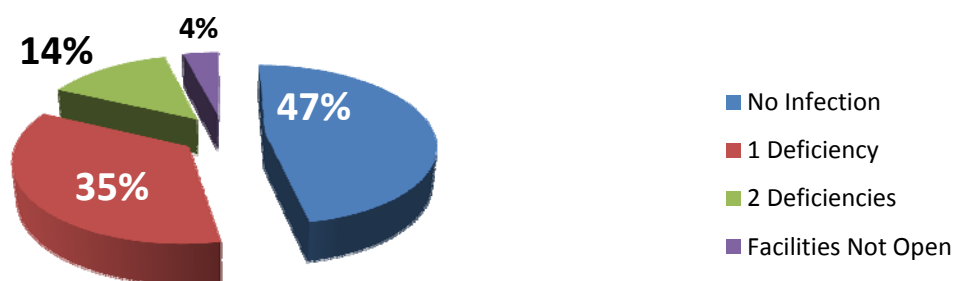
Due to the breadth of the concern, the Governor mandated that all such facilities be evaluated as soon as possible for similar breaches in infection control practices and medication administration, two issues which appeared to be central to the outbreak. On March 6, 2008, emergency regulations addressing safe injection practices were signed by the Governor, and the State Board of Health adopted permanent regulations addressing safe injection practices and other infection control practices on June 19, 2008. The permanent regulations were approved by the Secretary of State, effective October 25, 2008.

In 2008, the Health Division conducted surveys of all ASCs in Nevada to assess the scope of the problem and to further identify inadequacies in infection control practices and medication administration. At the time of exposure, there were 51 licensed ASCs statewide, one was temporarily closed for remodeling, and another had not yet opened. 50 ASCs were CMS certified, and 32 had been accredited by an approved third-party accrediting body.

In total, 49 focused surveys were conducted, with CDC participation and assistance. Twenty-five ASCs were identified as having infection control type deficiencies. Of all 49, 35% had 1 infection control category deficiency and 14% had 2. Two were not open during this period, thus could not be inspected. No such deficiencies were noted at the other 24.

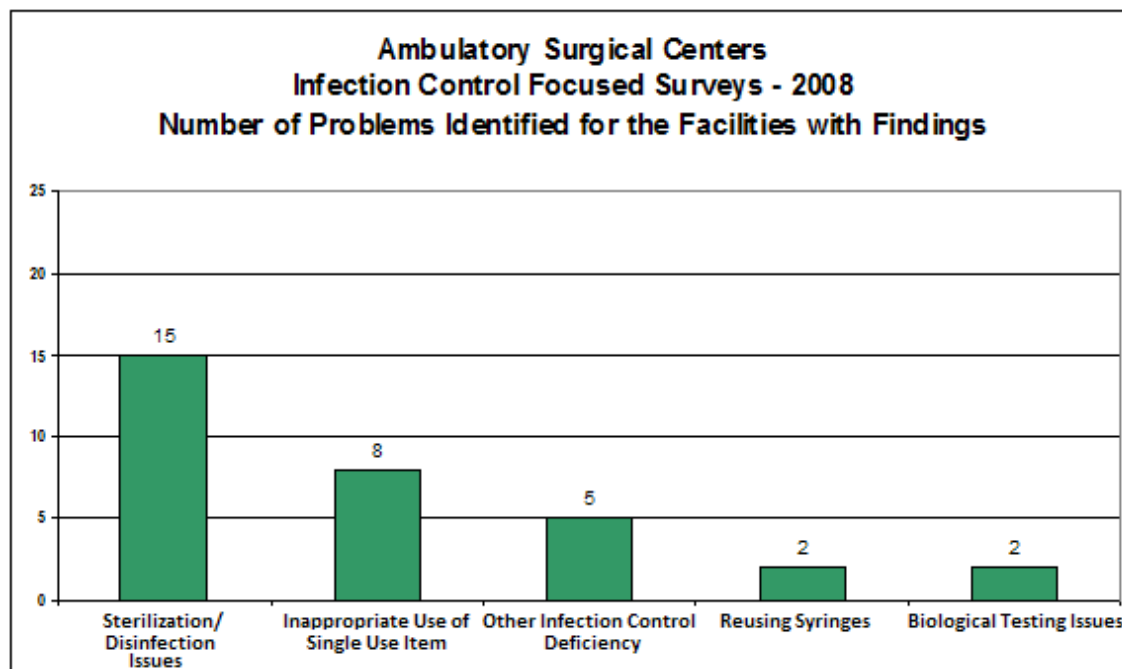
Figure 1

Deficient Facilities CY 08 by Number of Infection Control Category Deficiencies



Sterilization and disinfection issues were the most frequently noted infection control deficiency, accounting for almost half, while inappropriate use of single use items, including syringes, amounted to nearly a third. Among the remaining infection control issues were training and biological testing procedures. For a list of the top five deficiencies across all categories, see Appendix A.

Figure 2



Following the state's focused survey efforts, CMS ordered that an additional 28 Medicare surveys be done to assess compliance with all federal standards. Eighteen were conducted by the state with the oversight of and participation by CMS regional office staff and 10 were done by BHCQC. This round of surveys revealed that 61% had some level of infection control deficiency, 14% had single-dose vial and syringe reuse issues, and 64% had 'condition level' non-compliance issues, meaning the health and safety of patients could be jeopardized. Overall, 93% of the 28 surveyed ASCs received some level of federal citation. For more detail on deficient facilities by deficiency type, see Appendix C, and for a list of the top five deficiencies across all categories, see Appendix B.

As a result of the federally-mandated inspections, the following 5 ASCs were involuntarily terminated from the Medicare program: Endoscopy Center of Southern Nevada, Desert Shadow Endoscopy Center, Shadow Mountain Surgical Center, Digestive Disease Center, and Gastrointestinal Diagnostic Center.

AMBULATORY SURGICAL CENTERS

Definitions and Role

NRS 449.019 defines a 'surgical center for ambulatory patients' as:

'a facility with limited medical services available for diagnosis or treatment of patients by surgery where the patients' recovery, in the opinion of the surgeon, will not require care as a patient in the facility for more than 24 hours.'

42 CFR 416.2 states that an 'ambulatory surgical center' is:

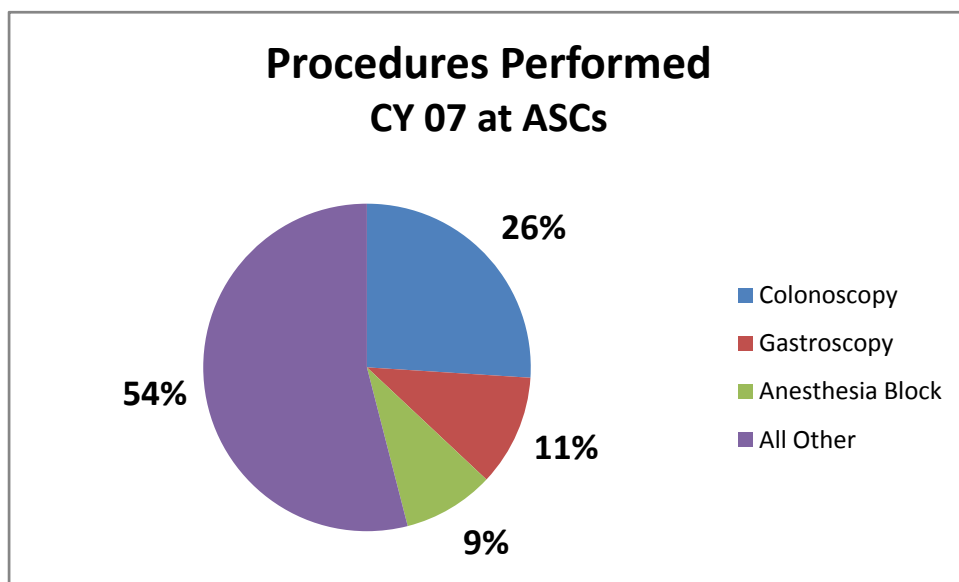
'any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets' the other conditions of this code

In general, ASCs are medical facilities that specialize in elective same-day or out-patient surgical procedures. They do not offer emergency care. Patients treated at ASCs do not require admission to a hospital and are well enough to return home following a procedure.

Procedures

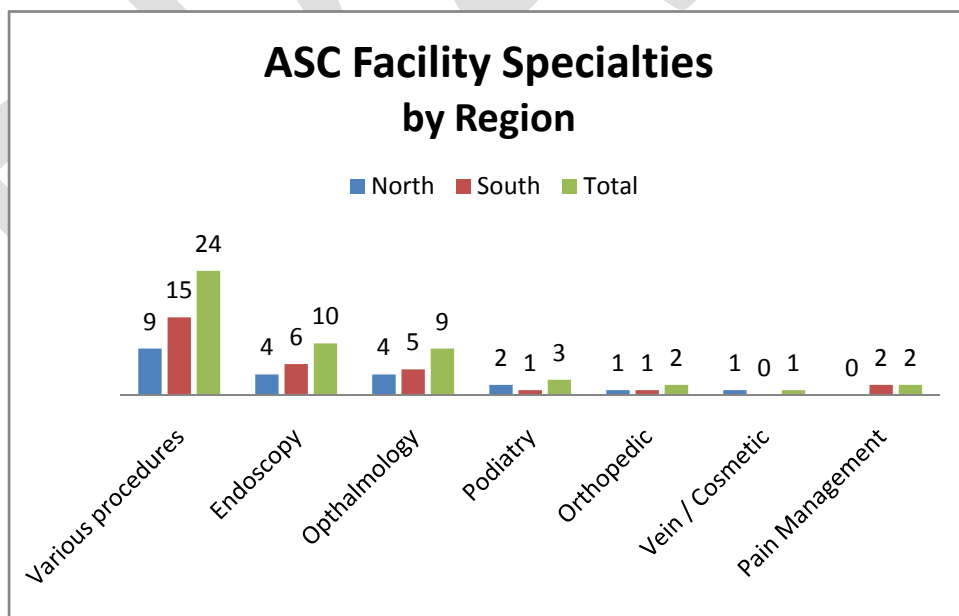
ASCs perform wide range of procedures. In the 1980s and 1990s, many surgeries and procedures that used to be performed exclusively in hospitals began taking place in ASCs. According to the Nevada Hospital Quarterly Reports (NHRQ), of the 200,048 total procedures performed in CY 2007, 70% were done at ASCs and 30% at hospitals. Many knee, shoulder, spine, eye, and other surgeries are currently performed in these facilities as well as other procedures such as pain management, bronchoscopy, and colonoscopy. The three most common procedures performed at ASCs were colonoscopy, gastroscopy, and anesthesia block (Figure 3.). For a more detailed list of procedures, see Appendix D.

Figure 3



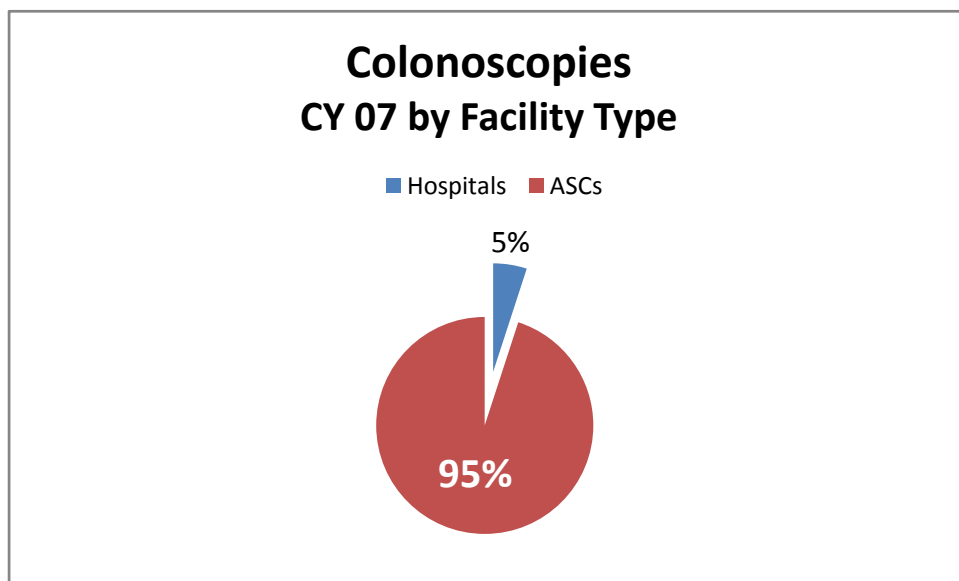
Most ASCs in Nevada perform a variety of services. In fact, almost half do; however, a significant share specializes in a certain category of procedures. The two most common categories of procedures are endoscopy and ophthalmology at 20% and 18% respectively.

Figure 4



Colonoscopies, a focus of the Hepatitis C investigation, accounted for 19% of the total procedures in CY 2007. Of these, 95% were performed at ASCs while 5% were in-patient.

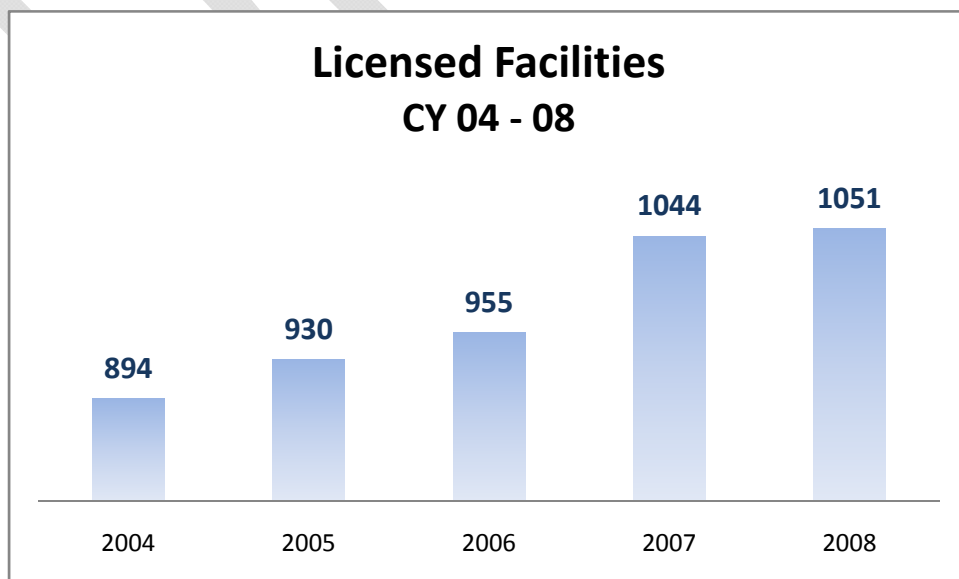
Figure 5



Presence and Growth

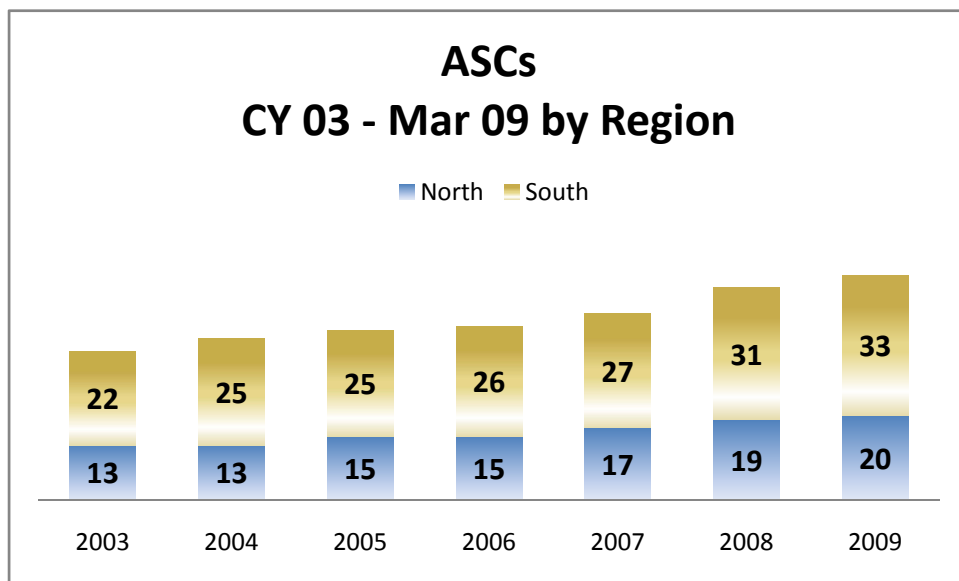
From July 1985 to July 2008, Nevada has been among the four fastest-growing states. Accompanying this growth has been a rise in the number of medical facilities and out-patient procedures performed. Figure 6 shows the number of licensed health facilities for the past 5 years.

Figure 6



As of February 19, 2009, Nevada had 53 licensed ASCs, all CMS certified. Thirty-seven have also been nationally accredited. Figure 7 shows the number of ASCs per region for the last 7 years.

Figure 7



GOVERNMENTAL ROLES AND RESPONSIBILITIES

Purpose

What became clear in the wake of the Hepatitis C outbreak was that beyond the individual facilities implicated, a system failure had occurred that allowed dangerous industry practices to continue in the absence of swift corrective action. The extent of the failure was both complex and multi-party. Therefore, in order to eliminate the root cause of the problem, a better understanding of the contributing elements was necessary. Hence, the Health Division decided to adopt a systems approach to analyzing the problem. This recognized the importance of affecting system-wide change because merely correcting an apparent concern—syringe use at a given facility, for example—fails to address its precursors, thus allowing both the factor and risk to persist.

Organization

The following sections are devoted to examining the current governing system and indicating what specific actions have been taken, ultimately with the hope of identifying gaps between what can and what needs to be done. The first section describes the various roles and responsibilities of the state and notes what immediate actions were taken under each in response to the Hepatitis C outbreak. The subsequent section outlines lessons learned from the outbreak and explains what reforms were made having incorporated their key messages. Finally, an action plan is presented by the Health Division that seeks to specify areas where the state's effort to protect the public could be facilitated through policy. These proposed modifications will help ensure that health care facilities provide quality services and operate at a higher level of safety.

Authority

Regulated by the State Board of Health and State Health Officer, pursuant to NRS 439 and 449, the Bureau of Health Care Quality and Compliance (BHCQC) is responsible for the licensure and certification of health care facilities and medical laboratories in Nevada. The Health Facilities section of BHCQC handles all licensing and certifying activities. The mission of the BHCQC is as follows:

‘To protect the safety and welfare of the public by promoting and advocating quality health care through licensure, regulation, enforcement, and education.’

Licensure

Statutory and regulatory licensure requirements for health facilities exist at both the federal and state levels. With the exception of a few facility types, a state license is required by the Health Division before any health care facility may begin providing services. In Nevada, there are approximately 31 distinct types of facilities, including ASCs, which require licensing and periodic oversight. To continue operating, a facility must renew its license annually by December 31. For ASCs, the initial licensing fee is \$3,570 with renewals set at \$1,785. A significant part of the BHCQC survey workload is spent conducting initial surveys of new facilities, so they can become licensed to operate.

Certification

Although not required to operate, a health care facility may additionally seek certification from CMS to qualify for reimbursements through Medicare and/or Medicaid. However, since initial Medicare/Medicaid certification is a low priority for CMS, facilities, such as ASCs, often choose to obtain this certification from an approved accrediting organization.

To help deal with this situation, state health licensure agencies throughout the US have federal-state agreements in place with CMS to serve as its field agent. The Health Division has such an agreement and has further delegated the responsibility of conducting the federal certification surveys to its Health Facilities section, at the request of those wishing to receive reimbursement for providing medical services to Medicare and/or Medicaid enrollees. In addition to ensuring compliance with federal regulations related to quality of care, surveyors review life safety code requirements at the facilities to ensure they are in compliance with federal regulations.

Surveys and Inspections

Currently, there are no NRS or NAC provisions specifically designating how often to survey ASCs. As such, they are surveyed based on CMS stipulations, which requires that 5% of all ASCs be inspected or surveyed each year for non-deemed providers. Further, the state survey agency must perform validation surveys for 5% of all deemed ASCs. Current CMS policy specifies that no more than 7 years may elapse between surveys.

If certification has not been received, an ASC may achieve 'deemed status' via accreditation by a recognized third-party accrediting organization, such as The Joint Commission or the Accreditation Association for Ambulatory Health Care (AAAHC).

Interestingly, in 2002, the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS) issued a report entitled *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*. The report found that Medicare's system of quality oversight is not up to the task and lacks accountability; therefore, it recommended that CMS determine an appropriate minimum cycle for surveying ASCs certified by state agencies. In addition, the report stated that the Medicare Conditions of Participation for ASCs should be updated to address patient rights and continuous quality improvement. The Inspector General stressed that state agency certification must strike an appropriate balance between compliance and continuous quality improvement, rather than focusing on one or the other. The response from HHS was to launch a quality initiative under which members of the ASC industry, along with associations and related organizations with a focus on health care quality and safety, are working to identify specific measures for quality. Despite these stated goals, nothing has been done to address the periodicity of ASC surveys since the report was released 7 years ago.

As for the inspections conducted by BHCQC, each includes 5 essential activities:

1. Pre-inspection information gathering and facility file review
2. On-site information gathering and compliance determinations
3. Notifications to other entities when public health issues are identified
4. Citation of non-compliance and plans of correction when necessary
5. Application of sanctions when necessary

Action Taken

Regarding the essential inspection activities, changes are being or have been implemented to the third, fourth and fifth. Such changes are described below.

3 *Notifications to Other Entities When Public Health Issues Are Identified*

At some ASCs in southern Nevada prior to the Hepatitis C outbreak, the Health Facilities section did not have a standard policy for providing notification to other entities when a public health issue was identified in a health care facility. Public health concerns are now immediately relayed to community, state, and federal sources. The Health Facilities section has also developed a policy to ensure that notifications are made timely and uniformly, and a system of notification tracking has been implemented.

4 *Citation of Non-Compliance and Plans of Correction*

The Health Facilities section is currently working on improvements to the way deficiency reports (statements of deficiencies) are generated, reviewed, and delivered to health care facilities. In the past, mandatory supervisor review of statements of

deficiencies often resulted in their not being delivered to health facilities in a timely manner. Now, inspectors are allowed to generate abbreviated statements of deficiencies that are not subject to supervisor review for violations that have little or no immediate impact on patient care. These may be given to facility representatives on-site prior to departure from the inspection for prompt correction. Whenever it is determined that a higher level violation has occurred, the process then reverts back to detailed documentation and supervisor review.

5 *Application of Sanctions*

Prior to October 2008, the sanction process was not monitored thoroughly and sanctions were not always applied effectively. The Health Facilities section has refocused its efforts on this process by developing a sanction policy to ensure consistent application and creating a system for sanctions tracking. There is a wide range of state sanctions available to encourage health facilities to comply with statutes and regulations including monetary fines, denial of applications for licensure, summary suspensions of licenses, and revocations of health care facility licenses. In addition, facilities certified for CMS reimbursement are subject to enforcement rules according to federal standards. Since October 2008, numerous sanctions have been applied. Information about both health facility citations and sanctions is now published publicly on the BHCQC web page.

Complaint Investigations

The Health Division receives more than 1,100 complaints annually from a variety of sources, including recipients of care and their families. All complaints are triaged under an established system, which is outlined in Table 1.

Table 1 HCQC Complaint Priorities

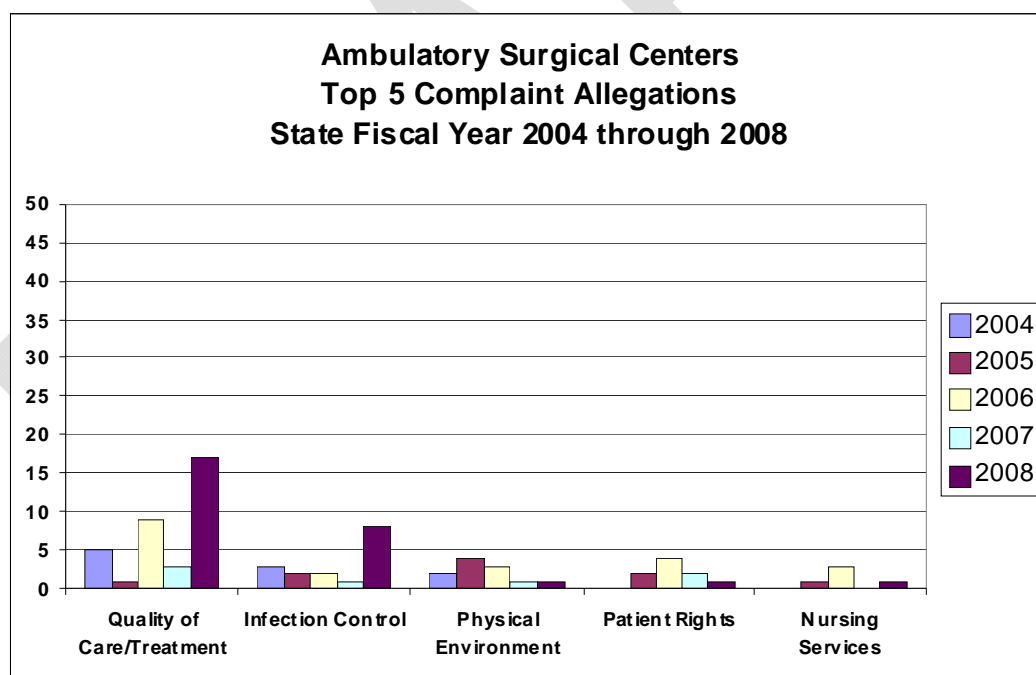
Priority	Time from Receipt to Investigation
State Requirements	
Unlicensed Adult Group Care	72 hours
Other unlicensed facilities	Dependent on established priority
Federal Requirements	
Immediate Jeopardy (IJ)	2 working days
Hospital Validation Complaint	5 working days
Emergency Medical and Treatment and Active Labor Act (EMTALA)	5 working days following CMS authorization
Restraint Seclusion Death Reports	
Non-IJ High	10 working days
Non-IJ Medium	45 working days

Some complaints require a team of highly specialized staff to conduct an investigation, which in turn can trigger a full federal or state survey that had not been anticipated. The Hepatitis C outbreak in 2008 is one clear example of this scenario. It required experienced registered nurse surveyors to review multiple facilities in order to assess safe injection practices and other infection control issues.

Analysis

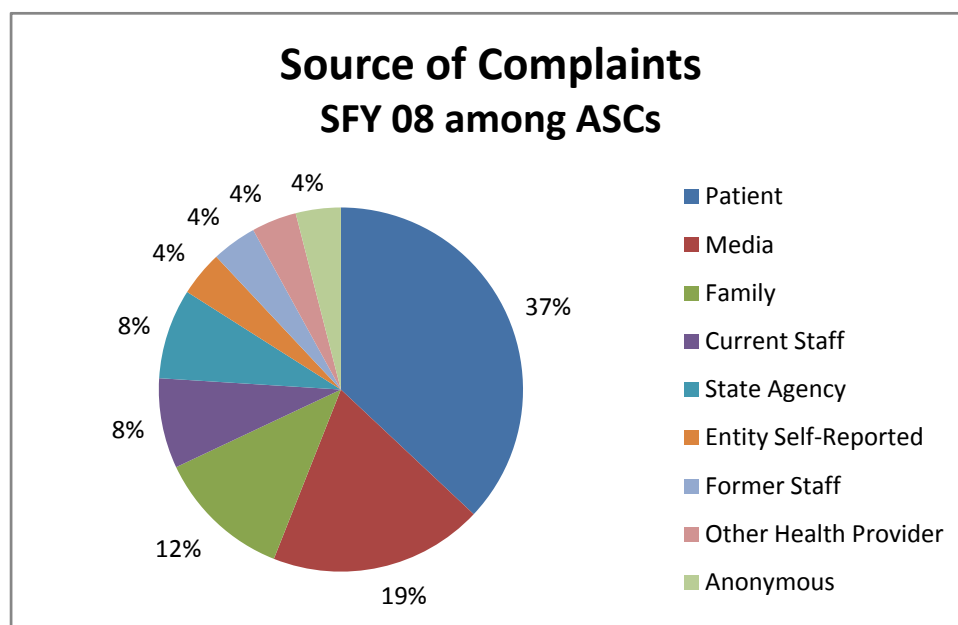
Prior to the Hepatitis C outbreak, the Health Division received relatively few complaints regarding ASCs, but with these facilities understandably in the spotlight throughout 2008, complaints about them increased from 22 between 2004 and 2007 to 25 for 2008 alone. Significant increases can be seen in SFY 2008 for both quality of care and infection control concerns. Well over half of the complaints related to quality of care or treatment, while about a third related to infection control. These have been the focus of the Health Division as it works with the ASCs and the health care industry to make sustainable system improvements. Figure 8 shows the top five types of allegations over the past 5 years.

Figure 8



As for the source of complaint, the top three were patients, accounting for 37%, family, 12%, and media, 19%. Current ASC staff members and state agencies both contributed 8%, the remainder accounted for 20%. Figure 9 illustrates the source of these complaints for SFY 08.

Figure 9



Action Taken

The Health Division hired an infection preventionist to focus more attention on appropriate practices in facilities and to assess whether the current inspection process is adequate to uncover serious breaches in infection control. This position interfaces with facilities and provides education and consultation about infection control best practices.

Sentinel Events Registry

Sentinel Events

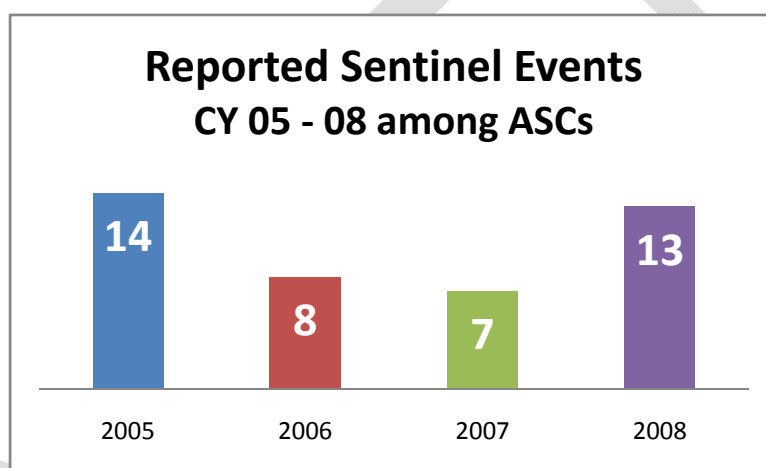
A sentinel is a mechanism put in place for the purpose of alerting authorities of an impending adverse event which might, nonetheless, be preempted before its full impact is felt with prompt and effective intervention. The Sentinel Events Registry was created with the purpose of treating adverse health events occurring in health care facilities as possible sentinels of wider-spread problems festering in a given health care facility type which might be remedied by the health care industry through quality improvement and/or education. This is important from a public health stand-point because correcting systemic problems can never be achieved on a case-by-case basis. Instead, corrective action must be directed to the root cause suggested by such cases or incidents. Nevada is moving toward

greater utilization of its reporting system to increase the robustness of data for analysis and identification of systemic trends.

Analysis

In CY 2005, mandatory self-reporting of sentinel events by various health care facilities, including ASCs, began. Since then, barely 600 sentinel events have been reported with only 42 originating from ASCs; however, in the context of the recent Hepatitis C outbreak, it is clear that such events are being under-reported. Nevertheless, consistent with a systems approach to ensuring quality health care, the data has been analyzed with the hope of providing some insight on the state of ASCs in Nevada before the reporting system has been improved.

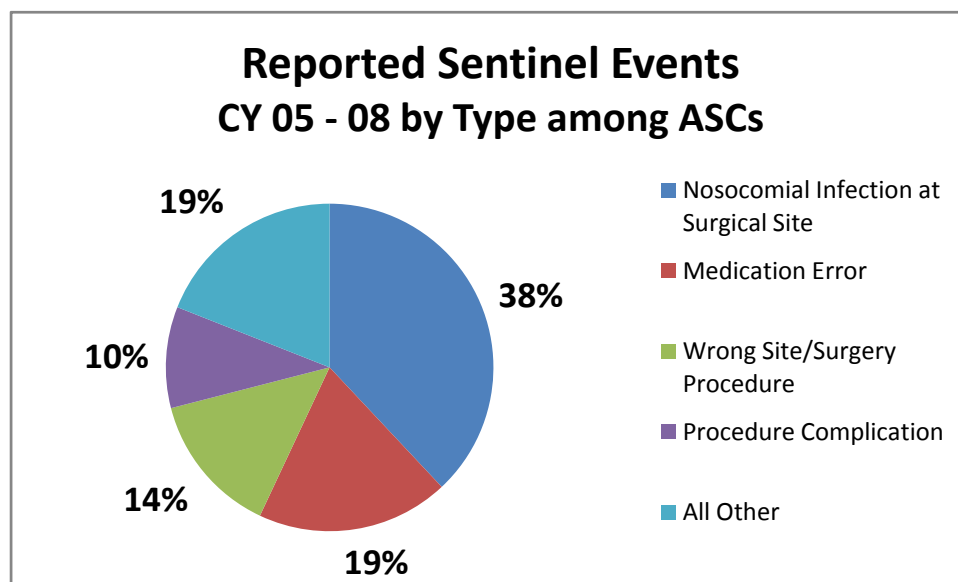
Figure 10



Looking at the types of sentinel events among ASCs reveals that nosocomial⁵ infections related to surgical site account for the largest share of sentinel events. This is to be expected of facilities performing surgical procedures, however minor. Medication error, improper site of surgical procedure, and procedure complications followed at 19%, 14%, and 10% respectively. The other category, accounting for 19% of sentinel events, includes treatment error, lost specimens, unexpected cardiac arrest, post-operative bleeding, burn, or laceration. Overall though, 62% of sentinel events directly involved surgical procedures, and it is likely that a share of medication error was also surgery related.

⁵ hospital-related

Figure 11



Furthermore, to elucidate where potential action might be taken to improve health outcomes in ASCs, the contributing factor information associated with the sentinel event was taken into account. Of the 42 sentinel event reports, 29 had contributing factor information, while 13 did not⁶. The sentinel events with contributing factors were then grouped, with the possibility of each being placed in more than one category. This list contained four contributing factor categories. The majority, 51%, of sentinel events in ASCs were wholly or partly attributable to staff-related actions. This included failure to follow policy or procedure, error in medical treatment or advice, clinical performance and administration, clinical decision and assessment, distraction, improper use of lasers, or being unaware or not mindful of patient allergy. However, failure to follow policy or procedure was the main source of staff-related sentinel events and, by itself, amounted to 22% of all contributing factors, the single most common factor.

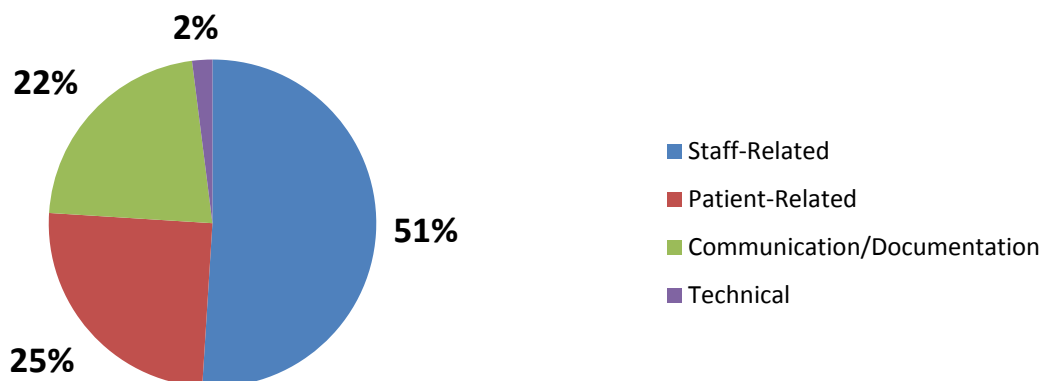
Among patient-related contributing factors, which accounted for 25% of the total, were patient allergy both known and unknown, adverse reaction to a medication, non-compliance, confusion, and/or frailty.

As a category, communication/documentation equaled staff-related failure to follow policy or procedure at 22%, and was largely characterized by inadequate or incorrect communication, or lack of thereof. Inadequate communication, in particular, accounted for 12% of all contributing factors. The remaining category, technical, involved various forms of incorrect dosing. Figure 12 presents these findings.

⁶ The 13 were thus excluded from the subsequent analysis.

Figure 12

Reported Sentinel Events with Contributing Factors CY 05 - 08 by Contributing Factor Category among ASCs



With regard to the outcomes of the sentinel events from 2005 to 2008, they ranged from no physical or psychological injury to actual injury or even death. Half involved risk of physical injury with permanent loss, while 10% resulted in actual physical injury with permanent loss. Another 14% carried the risk of psychological injury with permanent loss. Fortunately, 22% had no actual adverse outcome or risk of adverse outcome, but the remainder included either risk of or actual death. Altogether, 12% of all sentinel events among ASCs resulted in actual loss.

Action Taken

Given the range of outcomes and clear danger of the various failures, corrective action was taken by the ASCs to address not only the particular events but the underlying systemic factors contributing to their occurrence. This is an on-going process to protect public safety but which would benefit from more frequent self-reporting, more resources for timely analysis, and greater public-private interaction to better inform the public of the state of the health care industry. The table on the following page indicates the types⁷ of corrective actions taken by ASCs from 2005 through 2008 in response to sentinel events.

⁷ Note: There can be more than one corrective action for each reported sentinel event.

Table 2
CORRECTIVE ACTIONS TAKEN
from 2005 through 2008 by ASCs

	#	%
Procedure Review	18	19.6
Policy Review	17	18.5
Staff Education/In-service Training	11	12.0
Process Review	11	12.0
Procedure Modification	9	9.8
Policy Modification	6	6.5
Situation Analysis	6	6.5
Policy & Procedure Development	4	4.3
Unreported	3	3.3
All Other	7	7.6

Health Division Policy and Procedures Modifications

In addition to the actions taken indicated above, the matrices on the following two pages outline in detail many of the other changes the Health Division has made internally in response to the Hepatitis C outbreak. Many deal directly with the consequences of the outbreak, but others intend to strengthen the monitoring and inspection process of health care facilities and provide the public regular updates regarding such activities.

State of Nevada Health Division

Actions taken in response to the Hepatitis C Outbreak

REGULATORY ACTIONS AND POLICY AND PROCEDURES MODIFICATIONS

Revision 2009.2.19

Issues:	Regulation: State of Nevada Health Division Board of Health
Regulations	Emergency regulations were signed by the Governor on March 6, 2008. Permanent regulations were adopted by the Nevada State Board of Health on June 19, 2008 and were then signed off by the Secretary of State and became effective on October 25, 2008.

Issues:	Policy & Procedures: State of Nevada Health Division
Complaints	<p>Health Division has revised the Health Division website and made it user-friendly to educate and better serve the public by providing a "no wrong door" approach to complaint reporting and patient safety education. Additionally, the bureau has created a listserv. Both can be viewed at health.nv.gov.</p> <p>Changing the way we communicate with complainants so they don't have to wait for a Statement of Deficiency (SOD) to be issued but will receive a phone call and a letter outlining what we did to look into their complaints.</p> <p>Working with other professional licensing boards on ways to do joint investigations on complaints.</p> <p>Working on establishing an on-call, intermittent work-force to do complaints, including working with the Community Health Nurses in rural areas to do some initial investigations.</p>
Recruitment, Staffing, & Structure	Health Division, Human Resources has implemented many of the strategies proposed in the recruitment plan prepared in March 2008. As of January 14, 2009, there are no vacant Health Facility Surveyor positions. The vacancy rate over the past ten months has gone from 25.7% to 0%. HR is now focused on retention issues and strategic planning for the future. Three contract positions have been filled to focus on complaint investigations as well as a systems analyst.
Training	Health Division has partnered with Southern Nevada Area Health Education Centers (AHEC) and developed internet-based standard infection control curriculum based on CDC guidelines. The curriculum can be viewed both at health.nv.gov as well as snahec.org .
Health Literacy Education	Health Division has partnered with the State Medical Association to initiate a patient safety campaign in Nevada utilizing the HonoReform methodology and concepts. Campaign launch date was scheduled for February 11, 2009.
Data & Reporting	<p>Health Division staff have been working on the standardization of medical facility data collection, the annual medical facility data report and the standardization of the statement of deficiency reports. The annual report on Ambulatory Surgical Centers will be released in February 2009.</p> <p>Health Division has partnered with the State of Arizona to replicate their electronic posting software capabilities for statement of deficiencies – this has streamlined Statement of Deficiency (SOD) postings. The postings are now being done electronically versus the past manual input.</p> <p>Health Division has been issuing press releases to keep the public informed on how emerging facility issues are being addressed.</p>

State of Nevada Health Division

Actions taken in response to the Hepatitis C Outbreak

REGULATORY ACTIONS AND POLICY AND PROCEDURES MODIFICATIONS

Revision 2009.2.19

Issues:	Policy & Procedures: State of Nevada Health Division
Infection Control	<p>The State Health Officer, Nevada Advisory Committee on Infection Control will be releasing its recommendations soon.</p> <p>Require focused infection control survey, standardization of infection control procedures and the use of a standardized infection control tool. Certified Infection Control Health Facilities Surveyor has been hired to focus on infection control policy and procedures and to train Division and facility staff.</p> <p>Health Division has partnered with Southern Nevada Health District and the Association of Infection Control Professionals in a statewide Infection Control Symposium to be held in April 2009. The target audience will be infection control professionals from Skilled Nursing Facilities and smaller acute care hospitals.</p>
Communications	<p>Health Facility Surveyor work performance standards have been revised to include the following language: Immediate notification to local health authority when a procedure or practice is identified that is a risk for patient exposure to blood-borne pathogens; immediate notification to licensing board when practice or procedure by a licensed medical provider is determined to be a factor in risk or harm to a patient; and business licensing authority notification just prior to issuing the Statement of Deficiency (SOD) to the provider if blood-borne pathogen or other significant infection control risk was identified.</p>
Resources & Support	<p>Health Division ongoing resource and support of local health authorities:</p> <ul style="list-style-type: none"> • Financial assistance concerning the Hepatitis C investigation • Bi-monthly epidemiologic team meetings • Monthly health officer meetings • State Epidemiologist liaison activities between health authorities and the CDC <p>Health Division staff is actively working with the National Association of County and City Health Officials (NACCHO) in creating a Hepatitis C toolkit.</p>
Accreditation	<p>The Health Division has established a Memorandum of Agreement with the largest accrediting body and is in the process of negotiating with the remaining to formalize reciprocal communications.</p>

LESSONS LEARNED

The Health Division had much to learn from the Hepatitis C outbreak. The list below presents some of the lessons learned paired with the actions taken to put them in practice. It is hoped that such reforms will help rectify the issues identified, but while many changes and improvements have been made, more will be required over the next biennium to create a reliable health care facilities monitoring and evaluation system for Nevada.

For the Agency

<u>Lesson Learned:</u>	<i>CMS survey priorities were not in the best interest of Nevada.</i>
<u>Action Taken:</u>	The periodicity of surveys has been restructured to balance CMS requirements with continuous quality improvement and public health needs. The Health Division has requested 11 new surveyors who will allow the agency to survey all state-licensed facilities every 18 months.
<u>Lesson Learned:</u>	<i>Opportunities to identify and correct deficiencies were missed because complaints were not investigated in a timely manner.</i>
<u>Action Taken:</u>	A separate complaint unit has been developed which will ensure that complaints are reviewed within the established timeframes, facilities with a high number of complaints are looked at comprehensively as opposed to on an individual complaint basis, and a high level of complaints are resolved.
<u>Lesson Learned:</u>	<i>No mechanism was in place to alert other government agencies with overlapping regulatory responsibility when a public health issue was identified at a health facility.</i>
<u>Action Taken:</u>	A policy and procedure, as well as a notification tracking system, have been developed and implemented.
<u>Lesson Learned:</u>	<i>The Health Division has a responsibility to communicate with accrediting bodies to assure mutual accountability for health care quality.</i>
<u>Action Taken:</u>	Information sharing agreements with these bodies are being negotiated. The Health Division has established a Memorandum of Agreement with the largest accrediting body and is in the process of negotiating with the remaining bodies to formalize reciprocal communications.

For the Public

<u>Lesson Learned:</u>	<i>There was no transparency of survey and complaint investigation results.</i>
<u>Action Taken:</u>	This information is now being made public, including being posted on the Health Division web site.

For Facility Providers

<u>Lesson Learned:</u>	<i>Statement of Deficiency notifications were not being provided to the health facilities in a timely manner.</i>
<u>Action Taken:</u>	A two-pronged solution is underway. Survey processes are being piloted that allow the surveyor to generate abbreviated statements of deficiencies for violations that have little or no immediate impact on patient/resident care (i.e. a violation that there is a lack of a written policy wherein the facility is required specifically to have a written policy). Supervisor review is being eliminated for the abbreviated statements of deficiencies, so that these reports may be generated on-site during an inspection and given to the facility representatives prior to departure from the inspection.
<u>Lesson Learned:</u>	<i>The sanction process was not properly monitored, and state sanctions were not always applied appropriately.</i>
<u>Action Taken:</u>	The Health Division has developed a sanction policy to ensure application of sanctions in a consistent manner. The overall intent is to promote quality health care in Nevada by assigning sanctions that will encourage facilities to comply with requirements.
<u>Lesson Learned:</u>	<i>Health facilities did not have specific objective criteria, by facility type, to assess their own compliance, and they were not partners in the process.</i>
<u>Action Taken:</u>	Self-attestation surveys are being developed, with specific, objective criteria for each type of facility regulated. Prior to an onsite survey, the facility would complete the self survey, and the surveyor would then verify the information. This will foster a partnership with each facility and educate them about how to successfully meet the regulations.

FUTURE ACTION PLAN

Systems Approach Findings

As a result of the systems approach to the Hepatitis C outbreak in Las Vegas, immediate corrective actions were taken by the Health Division and reforms made to internal policy and procedures; however, the analysis also identified areas where state intervention might help prevent such incidents from occurring again but where the necessary statutory or regulatory authority was lacking to intervene when a present danger is detected. The patient- and issue-centered bubble charts on the pages that follow were used to help the Health Division identify these gaps.

Statutory and Regulatory Modifications Proposed

Changes in a number of statutory and regulatory areas would permit the Health Division to be more effective in its oversight of medical facilities, including ASCs. First, statutorily defined frequency for inspections of all medical facility types would be a transparent and predictable method that would not only enable the state to identify and correct violations earlier, but also assure the public that health care facilities provide quality services in an environment that is safe and sanitary. For facilities that are in violation, more specific language regarding the Health Division's authority to fine the facilities would create an incentive for providers to operate at a higher standard and a means for the Health Division to take corrective action when violations occur.

Second, clarifying the language in statute regarding the powers of the state during an investigation of a medical facility:

- Allowing the State Board of Health to govern the closure of a medical facility
- Enabling the Health Division to take control of a facility's medical records
- Strengthening the authority of local health authorities to subpoena records

Third, in order to detect and potentially intervene before health care facility violations escalate in severity and risk the health and safety of the patients involved, the establishment of penalties for failure to report sentinel events would hopefully increase the regularity of reporting and thus provide a greater amount of data for the Health Division to analyze and determine when and where systemic failures are occurring.

In conclusion, the Health Division believes that the proposals summarized here above and in the following matrix are crucial to ensuring patient safety and infection control at ASCs and other health care facilities in Nevada and urges their consideration.

State of Nevada Health Division

Recommendations from the Hepatitis C Outbreak

STATUTORY AND REGULATORY PROPOSALS

Revision 2009.2.19

Issues:	Bill Draft Request: Related to Enhancing Authority over Medical Facilities in Nevada
Cease & Desist	Allow the State Board of Health to adopt regulations to specify the conditions under which a medical facility can be closed during an on-going investigation.
Penalties and Sanctions	Clarify statutory language as it relates to the power of the Health Division to fine medical facilities for violations.
Access/Protection of Medical Records	(a) Give authority to the Health Division to take control of a facility's medical records in the event the facility is closed during the course of an investigation. (b) Strengthen the authority of local health authorities or officers of health districts to subpoena records related to an on-going investigation of a medical facility.
Sentinel Events Reporting	Clarify statutory language related to sentinel events and establish penalties for facilities that do not report a sentinel event.
Disease Investigations & Cost Recovery	Clarify statutory language as it relates to the powers of local health authority or officer of a health district during disease investigations and establish methods to cover the costs of such disease investigations.
Sharing Information (Law Enforcement)	Clarify the method by which information in an investigation is shared with law enforcement authorities.

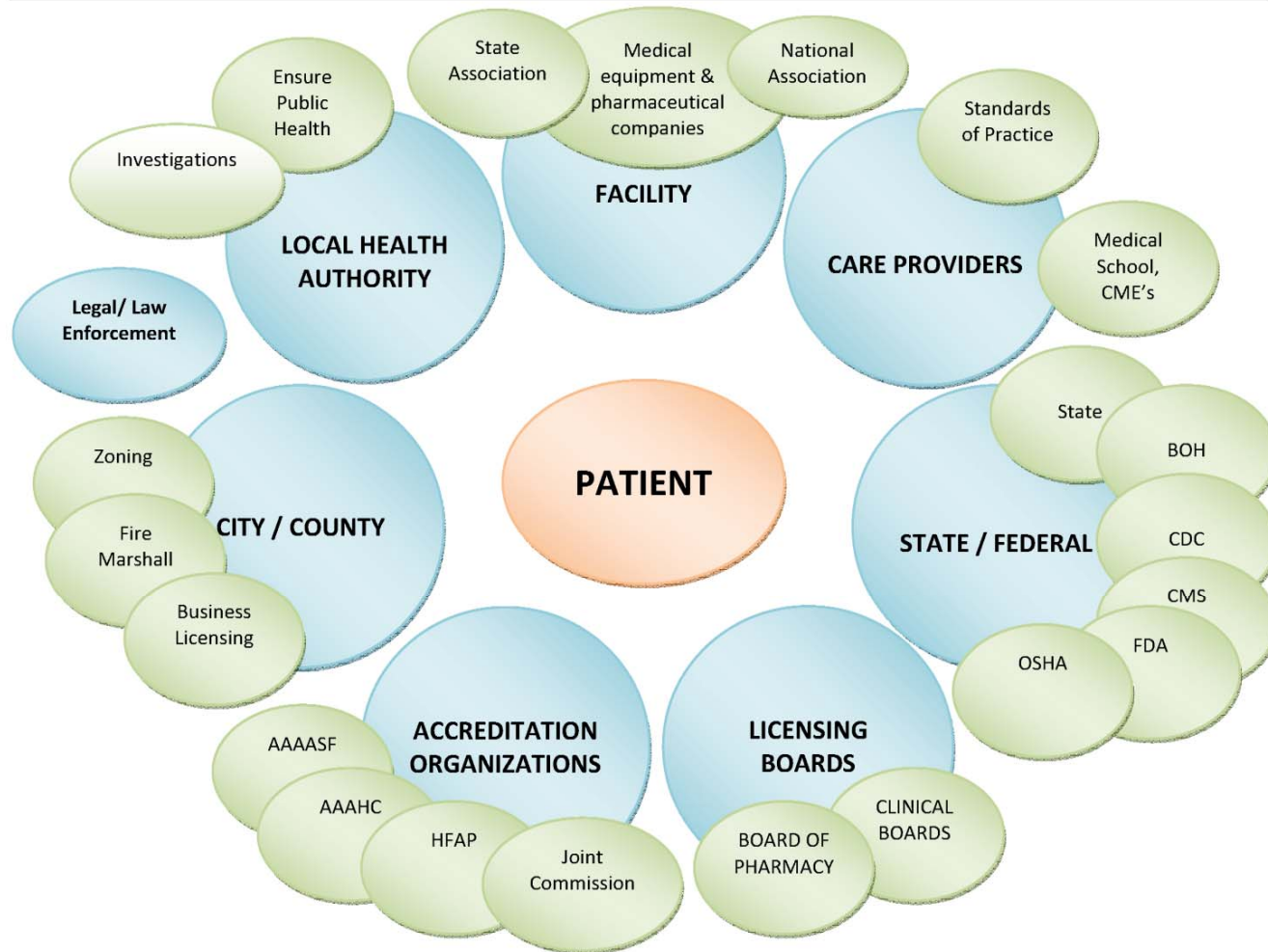
Issues:	Regulation: State of Nevada Health Division Board of Health
Frequency	Require that all facility types have a state frequency. Eighteen month periodicity proposed in budget – requesting an additional 14 positions: 11 Health Facility Surveyors, 1 Biostatistician, 1 Management Analyst, and 1 Administrative Assistant.

Nevada State Health Division

Recognizing the Components of Nevada's Health Care System: In Response to the Hepatitis C Outbreak

A NECESSARY STEP FOR ENSURING PATIENT SAFETY WITH REGARD TO INFECTION CONTROL

Revision 2009.2.24

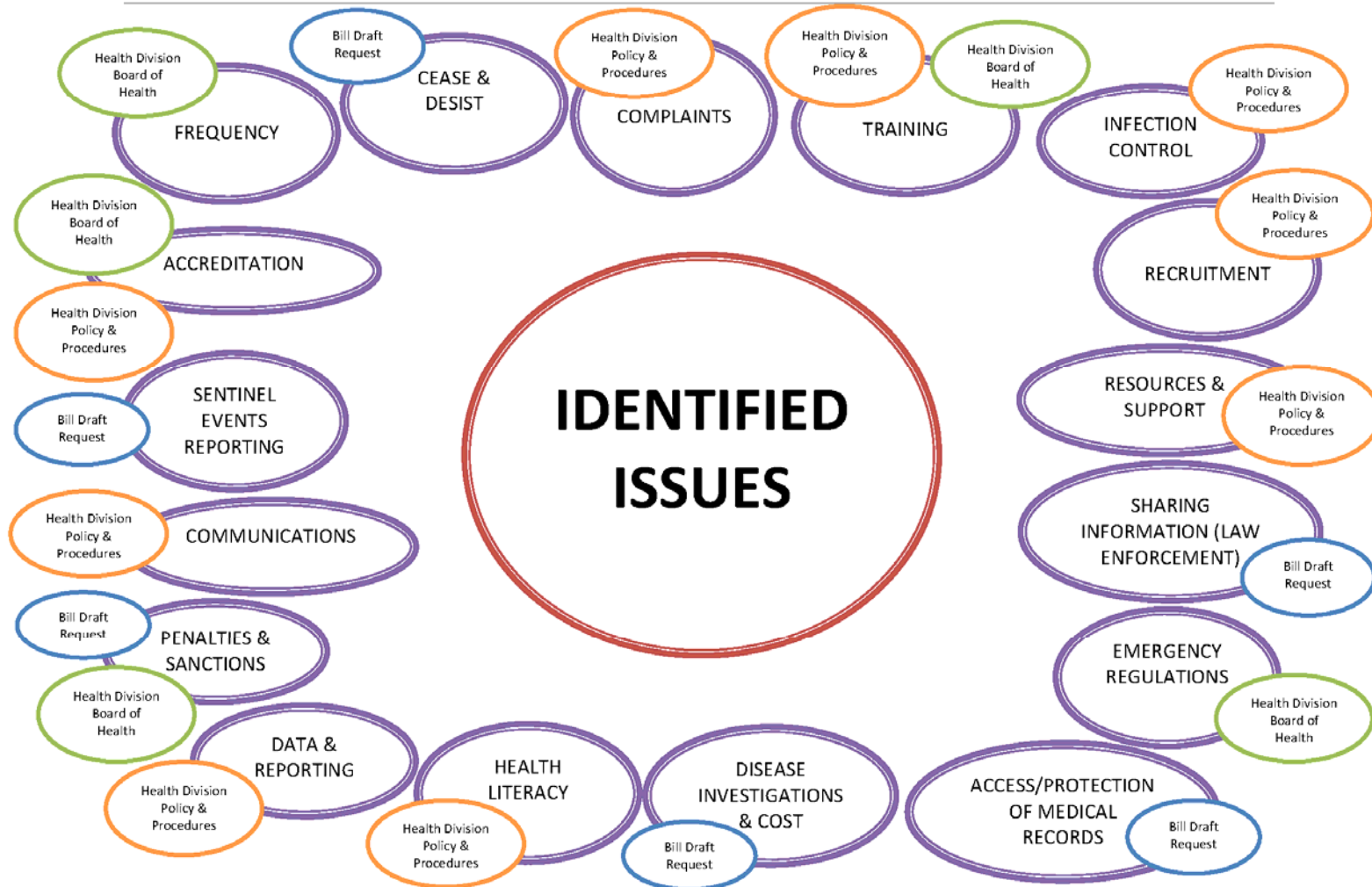


Nevada State Health Division

Response to the Hepatitis C Outbreak

IDENTIFIED ISSUES

Revision 2009.2.4



APPENDICES

Appendix A

Table 6
TOP FIVE CITED DEFICIENCIES
for SFY 08 among ASCs
STATE Regulations

	Nevada Administrative Code	Deficiency	# of ASCs Cited
1	Administration NAC 449.980 (7)(a)	Failure of the governing body to ensure that the center adopted, enforced and annually reviewed written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. Failure of the governing body to approved the policies and procedures annually.	12
2	Program for Quality Assurance NAC 449.9812 (2)(g)(6)	Failure to ensure that the program for quality assurance included, without limitation, procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing the procedures used to control infection.	11
3	Sterilization NAC 449.9895(4)	Failure to ensure the efficiency of the method of sterilization was checked not less frequently than once each month by bacteriological tests and records of the results of these tests were maintained by the center for at least 1 year.	8
4	Personnel NAC 449.9855 (2)(a)	Failure to ensure that each employee of the center had a skin test for tuberculosis in accordance with NAC 441A.375 and that a record of each test was maintained at the center	9
5	Emergency Equipment & Supplies NAC 449.9902 (1)(a)(b)(c)	Failure to be equipped with a cardiac defibrillator; a tracheotomy set; and such other emergency medical equipment and supplies as are specified by the members of the medical staff.	7

Appendix B

Table 7
TOP FIVE CITED DEFICIENCIES
for SFY 08 among ASCs
FEDERAL Regulations

	Code Federal Regulations	Deficiency	# of ASCs Cited
1	Physical Environment 42 CFR 416.44 (a)(3)	Failure to establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.	15
2	Administration of Drugs 42 CFR 416.48(a)	Failure to administer drugs according to established policies and acceptable standards of practice.	14
3	Emergency Equipment 42 CFR 416.44(c)	Failure to maintain emergency equipment available to the operating rooms.	13
4	Pharmaceutical Services 42 CFR 416.48	Failure to provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.	10
4	Governing Body and Management 42 CFR 416.41	Failure to have a governing body that assumed full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies were administered so as to provide quality health care in a safe environment. This included contracted services through outside resources.	10
5	Form and Consent of Record 42 CFR 416.47(b)	Failure to maintain a medical record for each patient and to assure that every record was accurate, legible, and promptly completed.	8
5	Surgical Services 42 CFR 416.42	Failure to assure that surgical procedures were performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.	8
5	Environment 42 CFR 416.44	Failure to maintain a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.	8

Appendix C

Table 5
DEFICIENT FACILITIES
by Deficiency among ASCs
FEDERAL Survey

Deficiency	#	%
Pharmaceutical Service	9 of 28	32%
Governing Body	9 of 28	32%
Environment	7 of 28	25%
Surgical Services	7 of 28	25%
Evaluation of Quality	6 of 28	21%
Medical Staff	5 of 28	18%
Lab and Radiology Services	4 of 28	14%
Nursing Services	3 of 28	11%
Hospitalization	1 of 28	4%
Compliance to License Laws	1 of 28	4%

Appendix D

Table 3
PROCEDURES PERFORMED⁸
during CY 07 at ASCs
STATE OF NEVADA

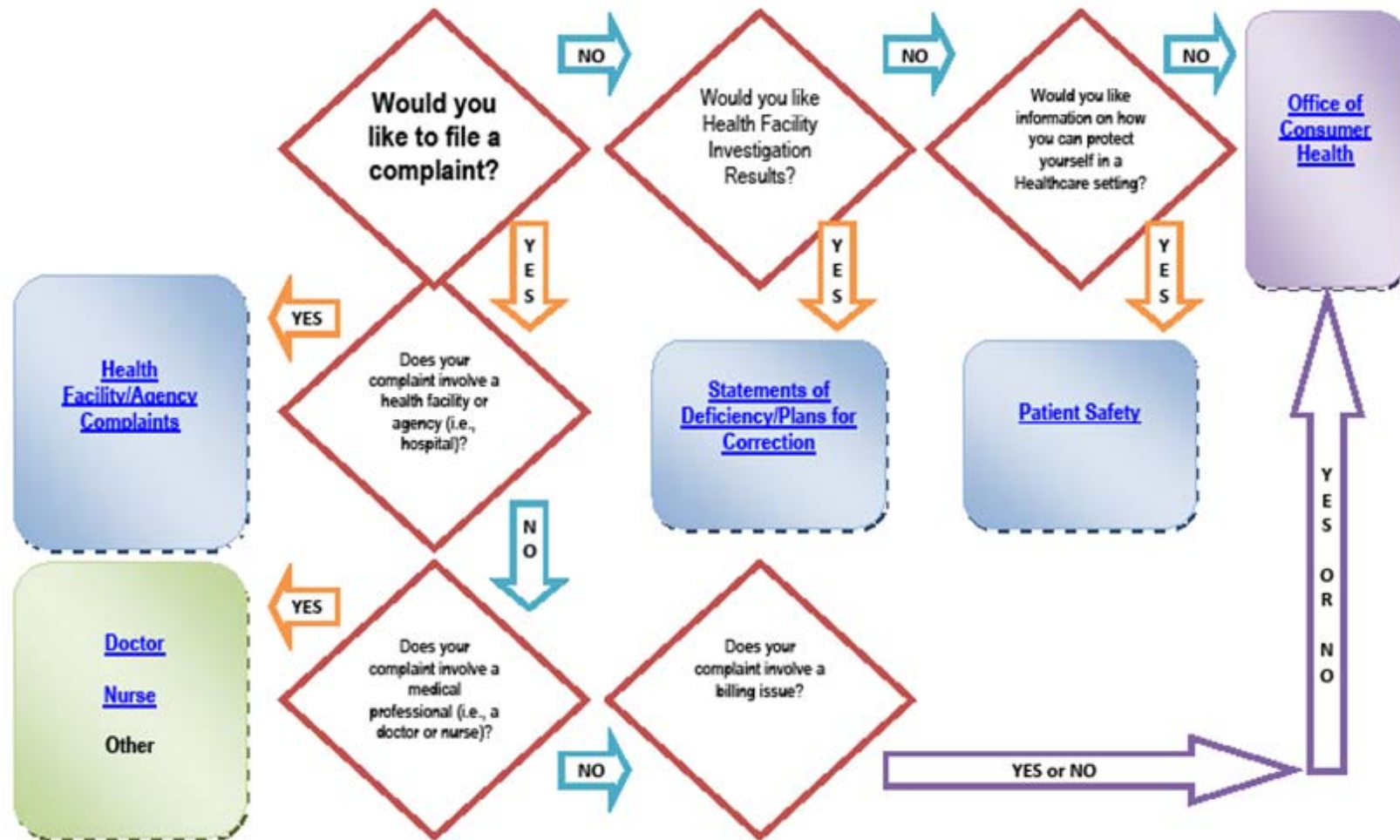
Procedure	#	%
Colonoscopy	36,454	26%
Gastroscopy	15,913	11%
Anesthesia Block	13,312	9%
Epidural - Lumbar	7,151	5%
Epidural - Cervical	2,780	2%
Pterygium	2,042	2%
Oral	1,556	1%
Plastic	1,256	1%
Epidural - Thoracic	764	0.5%
Sigmoidoscopy	1,016	0.1%
Bronchoscopy	96	< 0.1%
Other	58,119	41%
TOTAL	140,459	

⁸ Nevada Hospital Quarterly Reports (NHQR)

Appendix E

TOOLKIT FOR COMPLAINTS & PATIENT SAFETY EDUCATION FOR THE PUBLIC & HEALTH PROFESSIONALS

Flowchart for Navigating through the Nevada State Health Division's Patient Safety Website Link



Appendix F

Table 4
LICENSED HEALTH FACILITIES
as of February 31, 2008
STATE OF NEVADA

Medical Facilities

NRS Definition	Common Name	#	Remarks
Surgical Center for Ambulatory Patients	Ambulatory Surgical Center	53	
Obstetric Center		0	
Independent Centers for Emergency Care	Free-standing Emergency Room	1	
Agency Providing Nursing in the Home	Home Health Agency	125	
Home Health Agency Sub Unit		2	No NRS definition NAC449.749(5) defined
Home Health Branch		15	No NRS definition NAC449.749(1) defined
Facility for Intermediate Care	Nursing Home	2	Reimbursed by Medicaid
	Facility for the mentally retarded	8	
Facility for Skilled Nursing	Nursing Home	45	
Facility for Hospice Care		4	In-patient
Hospice Care-Program of Care		30	Out-patient
Hospital		60	acute, psychiatric, and long-term care; rehabilitation
Facility for Treatment of Irreversible Renal Disease	Renal Dialysis Center	35	
Rural Health Clinic		8	
Nursing Pool	Nurse Registry	39	
Facility for Modified Medical Detoxification		1	
Facility for Refractive surgery		2	
Mobile Unit		0	
Community Triage Center		2	For the mentally ill or chronically inebriated

Dependent Care Facilities

NRS Definition	Common Name	#	Remarks
Facility for the Treatment of Abuse of Alcohol or Drugs		19	
Facility for the Care of Adults During the Day	Adult Day Care	19	
Residential Facilities for Groups	Assisted Living Facility or Group Care	335	Includes Residential Care with an Alzheimer's Endorsement.
Facility for Transitional Living for Released Offenders		4	
Halfway Houses for Recovering Alcohol and Drug Abusers		5	
Agency to Provide Personal Care Services in the Home		14	

Other Miscellaneous Facilities

NRS Definition	Common Name	#	Remarks
Homes for Individual Residential Care		203	
Businesses that Provide Referral to Residential Facilities for Groups	Referral Agency	8	
Facility for the Treatment with Narcotics	Methadone Clinic	12	
Methadone Medication Unit		0	

Medicare Certified Facilities Not Requiring a State License

Medicare Definition	Common Name	#	Remarks
Comprehensive Out-patient Rehabilitation Facility		5	For individuals seeking comprehensive rehabilitation
Portable X-ray		4	
Rehabilitation Agency		16	

ACKNOWLEDGEMENTS

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Nevada State Health Division Technical Bulletin



Topic: Hepatitis C Investigation Section/Program:
Bulletin Number: Epi February 2008

TO: All Health Care Providers

TECHNICAL BULLETIN

Potential Exposure to Hepatitis C (HCV) in an Ambulatory Surgical Center in Las Vegas

This technical bulletin and provider update summarizes our findings and actions, and provides recommendations and advice.

Through recent routine and active surveillance efforts, the Southern Nevada Health District Office of Epidemiology staff identified six cases of acute hepatitis C (HCV) infections. All six cases had undergone endoscopic procedures at the same ambulatory surgical center in Las Vegas in July and September 2007. Unsafe injection practices primarily reuse of syringes, and subsequent multi-use of single-dose medication vials, may have led to contamination of the vials and patient-to-patient transmission of the hepatitis C virus.

Health care related exposures are a well recognized but uncommon source of viral hepatitis transmission in the United States. Similar to this outbreak, the majority of outbreaks identified previously nationwide have been associated with unsafe injection practices, primarily reuse of syringes and needles or contamination of medication vials used for multiple patients. However, because of the long and variable incubation period and the fact that the majority of patients with HCV infection are asymptomatic, clusters of patients related to a specific healthcare setting might not be recognized.

When health care workers do not adhere to fundamental principles related to safe injection practices, it suggests that they fail to understand the potential for disease transmission. In addition, deficiencies related to oversight of personnel and failures to report breaches in infection-control practices result in delays in correcting the implicated practices. We believe that this outbreak could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications.

To prevent transmission of blood-borne pathogens, all healthcare workers should adhere to recommended standard precautions and fundamental infection control principles, including safe injection practices and appropriate aseptic techniques.

Injections are very safe when standard procedures are followed. Nevada State Health Division recommends the development of written up-to-date policies and procedures to prevent patient-to-patient transmission of blood-borne pathogens. Additionally these policies and procedures should be established and implemented among all staff involved in direct patient care.

Approved by: _____ Dr. Ihsan Azzam, State Epidemiologist



Nevada State Health Division Technical Bulletin



Topic: Hepatitis C Investigation Section/Program:
Bulletin Number: Epi February 2008

TO: All Health Care Providers

Nevada State Health Division strongly advises that physicians and other health care providers in the state undergo mandated education periodically in proper infection control procedures. When renewing their licenses, physicians should acknowledge completing such training within the past four years.

Nevada State Health Division is partnering with professional organizations, advisory groups, and is working closely with SNHD and CDC to address these issues.

Injection Safety

- Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use.
- Use single-dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use.
- If multiple-dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.
- Use aseptic technique to avoid contamination of sterile injection equipment and medications.

Adapted from Transmission of Hepatitis B and C Viruses in Outpatient Settings — New York, Oklahoma, and Nebraska, 2000–2002. MMWR 2003; 52(38):901-906.

Approved by: _____ Dr. Ihsan Azzam, State Epidemiologist